Clinical Scenario

Aortic dissection – most common aortic emergency
- IRAD: 16 per 100,000 in men; 8 per 100,000 in women
- 1/3 Type B; 2/3 Type A
- OSR for acute, complicated TBAD carries high morbidity/mortality
- 50-80% operative mortality if complicated by renal/mesenteric ischemia

Clinical Scenario

Therapy attempts to stabilize aorta and promote remodeling
- Cover/exclude the Primary Entry Tear
- Treat or prevent rupture
- Expand true lumen; Regress false lumen; Induce false lumen thrombosis
- Alleviate distal malperfusion

Clinical Scenario

For acTBAD, TEVAR reduces early morbidity/mortality vs OSR
- TEVAR has become first-line therapy

The Medtronic Dissection Trial

Objective
Evaluate the clinical performance of Valiant Captivia for treatment of acute, complicated TBAD

Design
- N=50 patients, 16 US Centers
- Acute, Complicated TBAD with Malperfusion/Rupture
- Follow-up planned through 5 years

Enrollment: 2010 - 2012
FDA approval for TBAD: January 2014
Demographics and Medical History (N=50)

Cardiac history in 90% of subjects

- HTN: 72%
- ASA IV/V: 32%
- Vascular History: 32%
- Hyperlipidemia: 44%
- Renal Insufficiency: 12%
- Pulmonary: 9%
- Angina: 14%
- CAD: 12%
- CHF: 8%

Age: 57.2 ± 12.9 Years
Gender: 80% Male

Clinical Status at Onset (N=50)

- Back/Chest Pain: 88%
- Malperfusion: 72%
- Rupture: 20%
- Paraparesis: 12%

Malperfusion in 86% of subjects
- Visceral ischemia: 40%
- Renal ischemia: 42%
- Lower Limb: 40%
- Spinal Cord: 6%

Antihypertensives administered to 84%
Ionotropic support required in 16%

Procedural Data (N=50)

- 100% Delivery and Deployment Success
- Primary entry tear covered in 100% of subjects
- No misaligned deployment
- Device Oversizing: 12.0 ± 10.3%
- Length of Coverage: 196.9 ± 67.1 mm

All-Cause Mortality

- 4yr FF All-Cause Mortality: 76.8%

Dissection-Related Mortality

- CEC Adjudicated Mortality
  - Day 0, Cardiac tamponade
  - Day 1, Mesenteric ischemia in totalis
  - Day 9, Septica
  - Day 26, Pulmonary embolism
  - Day 72, Cardiac arrest
  - Day 87, Pneumonia
  - Day 124, Cardiac arrest
  - Day 315, Respiratory failure
  - Day 432, Natural causes
  - Day 812, Pneumonia

Serious Adverse Events and 2nd Endovascular Procedures

- Related to Dissection: 4 patients (3 pts. extension endografts; 1 pt. coil + liquid embolic)
- Not related to dissection: 1 patient (LSA plug)
Aortic Remodeling through 4 Years

71.4% (35/49) had dissections extending to or past Ao bifurcation
- 42% (21/50) had >1 visible re-entry tear
- 28% (14/50) had 3 or more re-entry tears

<table>
<thead>
<tr>
<th>Stented Segment (Core Lab)</th>
<th>1-Year</th>
<th>2-Year</th>
<th>3-Year</th>
<th>4-Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum diameter of False Lumen*</td>
<td>75.9% (22/29)</td>
<td>83.3% (20/24)</td>
<td>85.7% (18/21)</td>
<td>87.0% (20/23)</td>
</tr>
<tr>
<td>Maximum diameter of True Lumen (increased or stable)</td>
<td>93.1% (27/29)</td>
<td>95.8% (23/24)</td>
<td>95.2% (20/21)</td>
<td>100% (23/23)</td>
</tr>
<tr>
<td>Partial or Complete False Lumen Thrombosis</td>
<td>93.9% (24/26)</td>
<td>100% (20/20)</td>
<td>95.7% (22/23)</td>
<td>96.0% (24/25)</td>
</tr>
</tbody>
</table>

* Aortic lumen diameter change ≥ 5mm from 1st post-procedural imaging.

Summary Findings

Valiant Captivia continues to demonstrate positive outcomes through 4-years for acute, complicated TBAD patients
- 100% delivery / deployment success; All proximal entry tears excluded
- Aortic stabilization through 4-years; Only 1 dissection-related mortality after 30 days
- No ruptures and low 4% RTAD rate given the friable acTBAD pathology
- Favorable aortic remodeling with low need for 2nd endovascular procedures

Conclusions

- These 4-year, mid-term results of the Valiant Captivia system in the treatment of acute, complicated Type B Aortic Dissection are encouraging
- Patients will continue to be followed through 5-years to assess the long-term durability of TEVAR for this challenging pathology of acTBAD

Thank You